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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0053]

Medical Device Inspection Evaluation Report; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled "Medical Device Inspection Evaluation Report." The report describes the outcomes of the Medical Device Inspection Evaluation pilot conducted between March 1, 1999, and February 29, 2000. The report was prepared by the University of California at Irvine Statistical Consulting Center from the information received on the evaluation forms submitted by medical device manufacturers who were inspected for their compliance with the quality system/good manufacturing practices (QS/GMP) during the time of the pilot.

DATES: Submit written comments on this report at any time.

ADDRESSES: Submit written requests for single copies of the report to the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the report to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the report.

FOR FURTHER INFORMATION CONTACT: Denise Dion, Division of Emergency and Investigational Operations (HFC–130), Office of Regional Operations, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5645, FAX 301–443–6919.

SUPPLEMENTARY INFORMATION:

NAD 1

I. Background

FDA is announcing the availability of a report entitled "Medical Device Inspection Evaluation Report." In the **Federal Register** of January 28, 1999 (64 FR 4426, January 28, 1999), at the close of all premarket and QS/GMP inspections conducted between March 1, 1999, and February 29, 2000, an FDA investigator provided a survey packet to the device firm's representative. This survey packet included a questionnaire, a postage-paid return envelope, and a cover letter to the company explaining the questionnaire's purpose. FDA officials; industry representatives; and Dr. Anita Iannucci, the survey coordinator/data analyst from the University of California at the Irvine Center for Statistical Consulting, signed this cover letter. To maintain confidentiality, the firms mailed their completed questionnaires directly to the university survey coordinator.

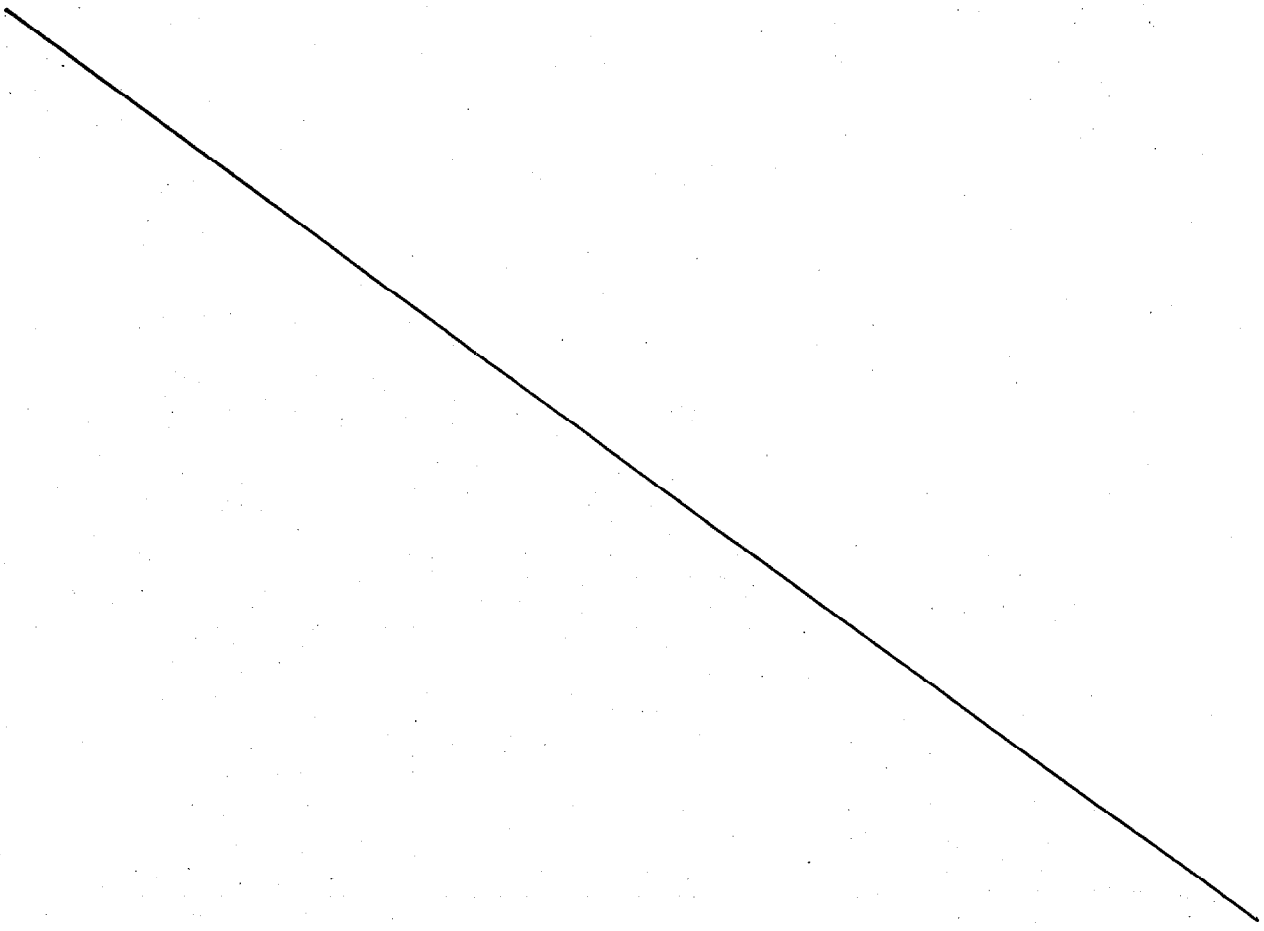
The purpose of the survey was to: (1) Give firms an opportunity to provide feedback to FDA and industry about their inspection experience, (2) compare the consistency of firms' reactions to inspections across different areas (both domestic and international), and (3) determine if the medical device industry initiatives (preannounced inspections and annotated FDA 483s) were being followed. The survey was also designed to determine if the initiative caused officials in medical device firms to view their FDA inspections in a more positive light than they had previously.

FDA's Office of Regulatory Affairs received the complete tabulation of the responses, and purged of all identifying information. FDA will be reviewing the report to determine if areas of future improvement can be identified. The information will be used internally to identify suggestions for training.

An FDA/industry committee consisting of: Nancy Singer, AdvaMed; Denise Dion, FDA; Lauren Andersen, AdvaMed and Andersen Caledonia Ltd.; Elaine Messa, Quintiles Consulting and Former Director of the Los Angeles District Office, FDA; Leif Olsen, AMDM and BioWhittaker; and Susan Reilly, ASQ Biomedical Division and Reilly and Associates, worked with Dr. Iannucci in designing the survey and assisting in the evaluation of the results. The committee members also assisted in the preparation of the final report.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the report at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the report and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/ora under the heading "Recent Publications."

Dated: 4-18-01
April 18, 2001.

Dennis E. Baker,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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